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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,043	04/03/2000	BERND EIKMANN	21437	6651

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EXAMINER

STEADMAN, DAVID J

ART UNIT PAPER NUMBER

1656

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,043

Applicant(s)

EIKMANN'S ET AL.

Examiner

David J. Steadman

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-118 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 91-108 is/are allowed.
6) ☒ Claim(s) 109-118 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: APPENDIX A
(sequence alignment)

DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[2] Claims 91-118 are pending in the application.

[3] Applicant's amendment to the claims, filed on 12/2/2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[4] Applicant's arguments filed on 12/2/2005 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[5] The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

Claim Objection

[6] Claim 110 is objected to as there is a period after "wherein said" in line 4 of part b), which prematurely ends the claim. Appropriate correction is required.

Claim Rejection - 35 USC § 112, Second Paragraph

[7] Claims 109-118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claim 109 is indefinite in the recitation of “substantially identical to...SEQ ID NO:2” as it is unclear from the specification and the claims as to how identical to SEQ ID NO:2 a sequence must be to be included within the scope of the claim. In the interest of advancing prosecution, the examiner has interpreted “substantially identical” to mean a sequence that has greater than 50% identity to SEQ ID NO:2. It is suggested that applicant clarify the meaning of the term “substantially identical” as it relates to SEQ ID NO:2.

[b] Claim 110 (claims 111-115 dependent therefrom) is confusing in the recitation of “aspartate and glutamate family strains..” as it is unclear as to the intended meaning of an aspartate and glutamate family strain. It is suggested that applicant clarify the meaning of the term.

[c] Claims 110 (claims 111-115 dependent therefrom) and 116 (claims 117-118 dependent therefrom) recite the limitation “the starting microorganism.” There is insufficient antecedent basis for this limitation in the claim.

Claim Rejection - 35 USC § 112, First Paragraph

[8] The new matter rejection of claim 109 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action.

RESPONSE TO ARGUMENT: Applicant argues the term “substantially” is supported by the specification at p. 8, line 7. However, this is not found persuasive because the disclosure at p. 8, line 7 of the specification is related to a DNA sequence and not a polypeptide. It is suggested that applicant show support for the limitation of “substantially identical to...SEQ ID NO:2.”

[9] The scope of enablement rejection of claim 109 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action.

RESPONSE TO ARGUMENT: Applicants argue the rejection is obviated by amendment.

Applicant's argument is not found persuasive. At least for the reasons of record, which are based on a determination by weighing all of the factual considerations of In re Wands, it is the examiner's position that the specification does not enable the claimed invention without undue experimentation.

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[10] Claims 110-112 and 116-118 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 110 (claims 111-112 dependent therefrom) and 116 (claims 117-118 dependent therefrom) are drawn to methods using a genus of transformed microorganisms that have increased "copy numbers" of pyruvate carboxylase.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses only a single representative species of the genus of recited transformed microorganisms, *i.e.*, a microorganism transformed with an expression

vector comprising a nucleic acid encoding SEQ ID NO:2. Other than this single disclosed species, the specification fails to disclose any additional species of the recited genus of transformed microorganisms, which encompasses widely variant species because the microorganism can have increased "copy numbers" of pyruvate carboxylase by *any* modification, including, *e.g.*, modification to endogenous promoter sequences, enhancer elements, and overexpressing transcription factors that regulate expression of pyruvate carboxylase.

Given the lack of description of a representative number of modified bacteria, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[11] Claims 110-112 and 116-118 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for practicing the claimed methods using a microorganism transformed with an expression vector comprising a nucleic acid encoding SEQ ID NO:2, does not reasonably provide enablement for the claimed methods using any microorganism as encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are so broad as to encompass the use of any microorganism having *any* modification that results in increased "copy numbers" of pyruvate carboxylase

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including, e.g., modification to endogenous promoter sequences, enhancer elements, and overexpressing transcription factors that regulate expression of pyruvate carboxylase. The specification discloses only a single working example of such transformed microorganisms, *i.e.*, a microorganism transformed with an expression vector comprising a nucleic acid encoding SEQ ID NO:2. Other than this single working example, the specification fails to provide any additional guidance for modifying a microorganism an expectation of achieving increased “copy numbers” of pyruvate carboxylase. The effects of modifying a microorganism with an expectation that the microorganism maintains the desired activity/utility is *highly* unpredictable. Because the specification fails to provide the necessary guidance, the experimentation required to make the full scope of recited transformed microorganisms is not routine. Thus, in view of the broad scope of the claims, the lack of guidance and working examples, the high level of unpredictability, and the amount of non-routine experimentation required, it is the examiner’s position that undue experimentation is required for a skilled artisan to make the full scope of recited microorganisms to practice the claimed methods.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

[12] Claim 109 is rejected under 35 U.S.C. 102(a) as being anticipated by GenBank Accession Number P95127 (May 1, 1997). Claim 109 is drawn to an isolated pyruvate carboxylase polypeptide that has an amino acid sequence that is "substantially identical" to SEQ ID NO:2.

P95127 teaches a pyruvate carboxylase polypeptide that is 64.2% identical to SEQ ID NO:2 herein (see Appendix A). This anticipates claim 109 as written.

Conclusion

[13] Status of the claims:

Claims 91-118 are pending.

Claims 91-108 appear to be in a condition for allowance.

Claims 109-118 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Thurs, 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656

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APPENDIX A

P95127_MYCTU

ID P95127_MYCTU PRELIMINARY; PRT; 1127 AA.
 AC P95127; Q7D6C5;
 DT 01-MAY-1997 (TrEMBLrel. 03, Created)
 DT 01-MAY-1997 (TrEMBLrel. 03, Last sequence update)
 DT 13-SEP-2005 (TrEMBLrel. 31, Last annotation update)
 DE PROBABLE PYRUVATE CARBOXYLASE PCA (PYRUVIC CARBOXYLASE) (EC 6.4.1.1)
 DE (Pyruvate carboxylase) (EC 6.4.1.1).
 GN Name=pca; OrderedLocusNames=MT3045, Rv2967c;
 OS Mycobacterium tuberculosis.
 OC Bacteria; Actinobacteria; Actinobacteridae; Actinomycetales;
 OC Corynebacterineae; Mycobacteriaceae; Mycobacterium;
 OC Mycobacterium tuberculosis complex.
 OX NCBI_TaxID=1773;
 RN [1]
 RP NUCLEOTIDE SEQUENCE.
 RC STRAIN=H37Rv;
 RX MEDLINE=98295987; PubMed=9634230; DOI=10.1038/31159;
 RA Cole S.T., Brosch R., Parkhill J., Garnier T., Churcher C.M.,
 RA Harris D.E., Gordon S.V., Eiglmeier K., Gas S., Barry C.E. III,
 RA Tekaia F., Badcock K., Basham D., Brown D., Chillingworth T.,
 RA Connor R., Davies R.M., Devlin K., Feltwell T., Gentles S., Hamlin N.,
 RA Holroyd S., Hornsby T., Jagels K., Krogh A., McLean J., Moule S.,
 RA Murphy L.D., Oliver S., Osborne J., Quail M.A., Rajandream M.A.,
 RA Rogers J., Rutter S., Seeger K., Skelton S., Squares S., Squares R.,
 RA Sulston J.E., Taylor K., Whitehead S., Barrell B.G.;
 RT "Deciphering the biology of Mycobacterium tuberculosis from the
 RT complete genome sequence.";
 RL Nature 393:537-544(1998).
 RN [2]
 RP NUCLEOTIDE SEQUENCE.
 RC STRAIN=CDC 1551 / Oshkosh;
 RX MEDLINE=22206494; PubMed=12218036;
 RX DOI=10.1128/JB.184.19.5479-5490.2002;
 RA Fleischmann R.D., Alland D., Eisen J.A., Carpenter L., White O.,
 RA Peterson J.D., DeBoy R.T., Dodson R.J., Gwinn M.L., Haft D.H.,
 RA Hickey E.K., Kolonay J.F., Nelson W.C., Umayam L.A., Ermolaeva M.D.,
 RA Salzberg S.L., Delcher A., Utterback T.R., Weidman J.F., Khouri H.M.,
 RA Gill J., Mikula A., Bishai W., Jacobs W.R. Jr., Venter J.C.,
 RA Fraser C.M.;
 RT "Whole-genome comparison of Mycobacterium tuberculosis clinical and
 RT laboratory strains.";
 RL J. Bacteriol. 184:5479-5490(2002).
 DR EMBL; BX842581; CAB05410.1; -; Genomic_DNA.
 DR EMBL; AE000516; AAK47371.1; -; Genomic_DNA.
 DR PIR; D70671; D70671.
 DR HSSP; P02905; 1A6X.
 DR HSSP; P24182; 1BNC.
 DR TIGR; MT3045; -.
 DR TubercuList; Rv2967c; -.
 DR GO; GO:0005737; C:cytoplasm; IEA.
 DR GO; GO:0005524; F:ATP binding; IEA.
 DR GO; GO:0009374; F:biotin binding; IEA.
 DR GO; GO:0016874; F:ligase activity; IEA.
 DR GO; GO:0004736; F:pyruvate carboxylase activity; IEA.
 DR GO; GO:0006094; P:gluconeogenesis; IEA.
 DR GO; GO:0008152; P:metabolism; IEA.
 DR InterPro; IPR011761; ATP_GRASP.
 DR InterPro; IPR011764; BC.
 DR InterPro; IPR001882; Biotin_BS.
 DR InterPro; IPR005482; Biotin_carb_C.
 DR InterPro; IPR000089; Biotin_lipoyl.
 DR InterPro; IPR005481; CPase_L_N.
 DR InterPro; IPR005479; Cphp_synth_L_D2.

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DR InterPro; IPR003379; PYC_OADA.
DR InterPro; IPR005930; Pyruv_carbox.
DR InterPro; IPR000891; PYR_CT.
DR InterPro; IPR000634; S/T_dehydrtse_BS.
DR Pfam; PF02785; Biotin_carb_C; 1.
DR Pfam; PF00364; Biotin_lipoyl; 1.
DR Pfam; PF00289; CPSase_L_chain; 1.
DR Pfam; PF02786; CPSase_L_D2; 1.
DR Pfam; PF00682; HMGL-like; 1.
DR Pfam; PF02436; PYC_OADA; 1.
DR TIGRFAMS; TIGR01235; pyruv_carbox; 1.
DR PROSITE; PS50975; ATP_GRASP; 1.
DR PROSITE; PS50979; BC; 1.
DR PROSITE; PS00188; BIOTIN; 1.
DR PROSITE; PS50968; BIOTINYL_LIPOYL; 1.
DR PROSITE; PS00867; CPSASE_2; UNKNOWN_1.
DR PROSITE; PS00165; DEHYDRATASE_SER_THR; UNKNOWN_1.
DR PROSITE; PS50991; PYR_CT; 1.
KW Complete proteome; Ligase; Pyruvate.
SQ SEQUENCE 1127 AA; 120422 MW; 84B0A4CC1A23CD90 CRC64;

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Query Match 64.2%; Score 3712.5; DB 2; Length 1127;
Best Local Similarity 64.4%; Pred. No. 8.5e-193;
Matches 730; Conservative 153; Mismatches 239; Indels 11; Gaps 6;

Qy	12	FKKILVANRGEIAVRAFAALETGAATVAIYPRDRGSFHRFSFASEAVRIGTEGSPVKAY	71
Db	2	FSKVLVANRGEIAIRAFRAAYELGVGTVAVYPYEDRNSQHRKKADESQIGDIGHPVHAY	61
Qy	72	LDIDEIIGAAKKVADAIYPGYGFLSENAQLARECAENGITFIGTPPEVLDLTGDKSRAV	131
Db	62	LSVDEIVATARRAGADAIYPGYGFLSENPDLAAACAAAGISFVGPSAEVLELAGNKSRAI	121
Qy	132	TAAKKAGLPVLAESTPSKNIDEIVKSAEGQTYPIFVKAVAGGGGRMRFVASPELKRKLA	191
Db	122	AAAREAGLPVLMSSAPSASVDELLSVAAGMPFPLFVKAVAGGGGRMRRVGDIAALPEAI	181
Qy	192	TEASREAEAAFGDGAVYVERAVINPQHIEVQILGDHTGEVHLYERDCSLQRRHQKVVEI	251
Db	182	EASREAESAFGDDPTVYLEQAVINPRHIEVQILADNLGDVIHLYERDCSVQRRHQKVIEL	241
Qy	252	APAQHLDPELDRDICADAVKFCRSIGYQGAGTVEFLVDEKGNHVFIEMNPRIQVEHTVTE	311
Db	242	APAPHLDAELRYKMCVDVAFARHIGYSCAGTVEFLDERGEYVFIEMNPRVQVEHTVTE	301
Qy	312	EVTEVDLVKAQMLRAAGATLKEGLTQDKIKTHGAALQCRITTEDPNNGFRPDTGTITAY	371
Db	302	EITDVDLVASQLRIAAGETLEQLGLRQEDIAPHGAALQCRITTEDPANGFRPDTGRISAL	361
Qy	372	RSPGGAGVRLDGAAQLGGEITAHFDSMLVKMTCRGSDFETAVARAQRALAEFTVSGVATN	431
Db	362	RTAGGAGVRLDGSTNLGABISPYFDSMLVKLTCRGRDLPTAVSRARRAIAEFRIRGVSTN	421
Qy	432	IGFLRALLREEDFTSKRIATGFIADHPHLLQAPPADDEQGRILDYLDVTVNKPVGVRPK	491
Db	422	IPFLQAVLDDPDPFRAGRVTTSFIDERPQLLTARASADRGTKILNFLADVTVNNPYGSRPS	481
Qy	492	DVAAPIDKLPNIKDLPL----PRGSRDLKQLGPAAAFARDLREQDALAVTDTTFRDAHQS	547
Db	482	TI-YPDDKLP---DLDLRAAPPAGSKQLRVKLGPGEFARWLRESAAVGVTDTTFRDAHQS	537
Qy	548	LLATRVRSFALKPAAEAVAKLTPELLSVEAWGGATYDVAMRFLFEDPWDRLDELREAMPN	607
Db	538	LLATRVRTSGLSRVAPYLARTMPQLLSVECWGGATYDVALRFLKEDPWERLATLRAAMPN	597
Qy	608	VNIQMLLRGRNTVGYTTPYDPSVCRAFFVKEAASSGVDFIFRIDALNDVSQMRPAIDAVLET	667

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Db	598	ICLQMLLRGRNTVGYTPYPEIVTSAFVQEATATGIDIFRIDALNNIESMRPAIDAVRET	657
Qy	668	NTAFAEAMAYSGDLSDPNEKLYTLDDYLLKMAEEIVKSGAHILAIKDMAGLLRPAAVTKL	727
Db	658	GSAIAEAMVCMYTGDLTDGPEQLYTLDDYLLKLAEQIVDAGAHVLAIKDMAGLLRPPAAQRL	717
Qy	728	VTALRREFDLPHVHHTDHTAGGQLATYFAAAQAGADAVDGASAPLSGTTSPQSLSAIVAA	787
Db	718	VSALRSRFDLPVHLHTDHTPGGQLASVVAAWHAGADAVDGAAAPLAGTTSPALSSIVAA	777
Qy	788	FAHTRRDITGLSLEAVSDLEPYWEAVRGLYLPFESGTPGPTGRVYRHEIPGGQLSNLRAQ	847
Db	778	AAHTEYDTGLSLSAVCALEPYWEALRKVYAPFESGLPGPTGRVYHHEIPGGQLSNLRQA	837
Qy	848	TALGLADRFEIENYAAVNEMLRPTKVTPSSKVVGDIALHLVGAGVDPADFAADPQKY	907
Db	838	IALLGLDRFEEIEEAYAGADRVLGRLVKVTPTSKVVGDIALALVGAGVSADEFPASDPARF	897
Qy	908	DIPDSVIAFLRGELGNPPGGWPEPLRTRALEGRSEKAPLTEVPEEEQAHLDADDKERR	967
Db	898	GIPESVLGFLRGELGDPGGWPEPLRTAALAGRGAAR-PTAQLAADDEIALSSVGAK-RQ	955
Qy	968	NSLNRLLPFKPTEEFLEHRRRFRGNTSALDDREFFYGLVEGRETLIRLPDVRTPLLRLDA	1027
Db	956	ATLNRLLPSPPTKEFNEHREAYGDTSQLSANQFFYGLRQGEHRVKL-ERGVELLIGLEA	1014
Qy	1028	ISEPDDKGMNRNVVANVNGQIRPMRVRDRSVESVTATAEKADSSNKGHVAAPFAGVVTVTV	1087
Db	1015	ISEPDERGMRVTMCIILNGQLRPLVLRDRSIASAVPAAEKADRGNPGHIAAPFAGVVTVGV	1074
Qy	1088	AEGDEVKAGDAVAIIIEAMKMEATITASVDGKIDRVVVAATKVEGGDLIVVVS	1140
Db	1075	CVGERVGAGQTATIEAMKMEAPITAPVAGTVERRAVSDTAQVEGGDLLVVVS	1127